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Patent- og Varemærkestyrelsen
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08 July 2004

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PATENT- OG VAREMÆRKESTYRELSEN

A CONNECTOR FOR A HAEMOSTATIC VALVE ASSEMBLY

Technical field

The present invention relates to a connector for a haemostatic valve assembly, as used for example in angioplasty. An elongate member, such as a balloon catheter or a vascular stent, may be introduced into the vascular system of a living through the connector which incorporates a haemostatic valve for safe haemostasis. In particular, the present invention provides an improved interconnection between a proximal and a distal part of a main section of a connector of the aforementioned type, and a means for reducing the risk of causing damage to a device to be inserted into the vascular system through the valve.

Background of the invention

Access to the vascular system of a living, such as a cardiac patient, is required during endovascular procedures such as in angioplasty, e.g., for the introduction of balloon catheters or stent systems. Usually, access is provided via a connector which, e.g., provides a connection to a guiding catheter, the connector integrating a haemostatic valve to enable an elongate device to be introduced into the body of the living while providing safe haemostasis. A side arm may be provided as a part of such a connector in order to provide a connection to a manifold used for pressure monitoring, contrast media injection and/or saline flushing. Connectors with side arms are normally referred to as 'Y-connectors'. The haemostatic valve ensures that blood does not flow out of the connector while enabling a catheter, stent system or arterirectomy device to be passed through the connector. At the distal end of the connector there may be provided a rotatable luer for securing the connector to a corresponding member at the proximal end of a guide catheter.

US patent No. 5,195,980 (David G. Catlin), discloses a haemostatic valve comprised in a Y-connector. The haemostatic valve is incorporated in a proximal end of a main section of the connector, which comprises a rotatable luer at its distal end. The side arm joins the main section between the distal end and the haemostatic valve. Another example of a haemostatic valve is known from US patent No. 5,176,652 (Perry K. Littrell).

The art of coronary angioplasty is generally described in: *Coronary Angioplasty* by Bernhard Meier, published by Grune & Stratton, Inc., Harcourt Brace Jovanovich, Publishers, 1987.

Summary of the invention

In a first aspect, the present invention relates to a connector for a haemostatic valve assembly having a main section being manufactured from two separate, co-extending parts which are mutually interconnected or joined, the two parts being preferably made from a plastics material. When interconnected, the two parts should be able to withstand a certain pressure in a longitudinal passage extending inside and being defined by inner surfaces of the two parts, such as an injection pressure. It has been found that it is sometimes difficult to manufacture an essentially glued interconnection between such separate parts of a connector, as it may not be easy to accurately control the manufacturing process such that the completed connector with certainty will be able to withstand a certain pressure. It is therefore desired to provide a connector for a haemostatic valve assembly comprising two separate parts, which connector does not rely on glue as the single or main means of interconnection of the two parts, while ensuring a relatively uncomplicated and cost efficient manufacturing process.

In a second aspect, the invention provides a connector for a haemostatic valve assembly, comprising a longitudinally extending main section with a valve at a proximal end thereof, the valve having an open state in which an elongate member may be inserted into the passage, and a closed state. Before introducing a device, e.g., a catheter or a drug-coated stent, through the connector and into the vascular system of a living, an operator, such as a physician, should ensure that the valve is properly opened, as otherwise an outer surface of the catheter or stent risks to scrape against parts of the valve, with the result that the surface of the device is damaged or that accurately dosed drug provided on the surface of a drug-coated stent is lost. However, given exterior circumstances such as in particular psychological stress, an operator may sometimes not verify that the valve is in its open state before attempting to introduce the device through the valve. Following an attempt to introduce the device through a closed valve, the operator may not always realise that drug has been scraped off the stent or that physical damaged has been caused to a surface of the device, and he may, after having properly opened the valve, introduce the device, now, for example, damaged or with a wrong dose of drug on the surface thereof, into the vascular of the patient. Such an incidence may seriously compromise the patient's health and does often result in the need for additional treatment and prolonged hospitalisation of the patient. Accordingly, it is an object of preferred embodiments of the second aspect of the invention to provide a means for reducing the risk of causing damage to a device to be inserted into the vascular system through the valve of a connector.

With the aim of at least partially solving some of the above problems, the first aspect of the present invention provides a connector for a haemostatic valve assembly, comprising a longitudinally extending main section having a proximal part and a distal part, each of said parts having a longitudinally extending, through-going passage, the connector further comprising connection means for providing a connection between the proximal part and the distal part, whereby, when interconnected, the distal and proximal parts coextend in the longitudinal direction, the connection means comprising a projecting portion which is integral with one of said parts and which is adapted to engage a recessed portion of the other one of said parts, so as to mutually secure the parts in the longitudinal direction. Thus, thanks to the essentially mechanical connection between the proximal and the distal part, the connector may be designed to withstand a given internal pressure, which may accurately be calculated based on specifications of the materials from which the two parts are made and on dimensions of the parts. In addition to the mechanical means provided at the interconnection, the interconnection may be reinforced by glue, though, in a presently preferred embodiment, the connector is assembled without glue. Preferably, the interconnection is formed as a snap-lock connection, e.g. a self securing snap-lock. In a preferred embodiment of the invention, the projecting portion is a barbed portion. The barbed portion may, for example, be provided as a part of an outer periphery of a first one of the two parts, the dimensions of which allows it to at least partially surround an end portion of a second one of the two parts. The surrounded part may thus provide a rim or a collar, e.g., at a transition between a small diameter section and a large diameter section thereof, which rim or collar the barbed portion may engage. The barbed portion preferably includes several barbs arranged along the periphery of the first part. In order to allow the barbed portion of the first part to be slipped over the second part, the barbed portion may be flexible in a radial direction, whereas it is preferred that it is not, or at least less, flexible in the longitudinal direction. Such radial flexibility may be brought about by longitudinally extending slits provided in an end portion of the first part. In one embodiment of the invention, an end portion of the distal part is adapted to receive an end portion of the proximal part, the barbed portion being provided at the proximal end portion of the distal part, the recessed portion comprising a collar portion, e.g. a sharp edged collar portion, provided on an outer surface of the proximal part. In other embodiments, the barbed portion may be provided at an end portion of the proximal part, which may receive an end portion of the distal part.

In order to preclude blood and/or other liquids from flowing out of the connector at the interconnection, there may be provided sealing means at the interconnection. Such sealing means may include a resilient member, such as an O-ring, which, when the proximal and distal parts are interconnected, is clamped between the two parts, for example such that it fits around and tightly closes an outer collar portion of an inner one of the two parts and such that it fits inside and tightly closes an inner collar portion of an outer one of the two parts.

The interconnection may be such that the distal part and the proximal part may rotate relative to each other around an axis extending in the longitudinal direction, such rotation being desired, e.g. if one or both of the two parts are provided with a threaded portion for engaging a thread of a corresponding member, such as of a guide catheter. In a preferred embodiment of the invention, the distal part constitutes a rotatable luer, so that there is no need for manufacturing a luer as a separate part. A first threaded or grooved portion may be provided on an outer and possibly conical wall of the distal part, whereas a second threaded portion may be provided on an inner surface of the distal portion. In the latter case, the threaded portion may be provided between an annular wall surrounding the longitudinally extending passage through the connector and a surrounding outer wall of the distal part, when seen in a radial direction.

The connector may be a Y-connector having a side arm, so as to provide a connection to a manifold used for pressure monitoring, contrast media injection and/or saline flushing. The side arm may be arranged to receive a tube which interconnects the side arm and a stopcock, such as a standard 3-way stopcock. The distal as well as the proximal parts of the connector may be manufactured by injection-moulding of a plastics material.

It should be understood that the connector according to the first aspect of the invention, as generally discussed above, may also include the features of the second aspect of the invention.

There is also provided a method for manufacturing a connector for a haemostatic valve assembly, in particular for manufacturing a connector according to the first or second aspect of the invention, the connector comprising a longitudinally extending main section having a proximal part and a distal part, each of said parts having a longitudinally extending, through-going passage, the connector further comprising connection means for providing a connection between the proximal part and the distal part, whereby, when interconnected, the distal and proximal parts coextend in the longitudinal direction, the connection means comprising a projecting portion which is integral with one of said parts and which is adapted to engage a recessed portion of the other one of the parts, the method comprising the step of providing a snap-lock between the projecting portion and the recessed portion for mutually securing the parts in the longitudinal direction. Injection-moulding is an appropriate manufacturing process for the distal and the proximal part.

The invention also provides a new use of a snap-lock as an interconnection between a longitudinally extending proximal and a longitudinally extending distal part of a main section of a connector for a haemostatic valve assembly, each of said parts having a longitudinally extending, through-going passage, the snap-lock comprising a projecting portion which is

integral with one of said parts and which is adapted to engage a recessed portion of the other one of said parts, so as to mutually secure the parts in the longitudinal direction. The connector may in particular be a connector according to the first or second aspect of the invention and may thus incorporate any feature of the connectors discussed above and below.

In order to reduce the risk of causing damage to a device to be inserted into the vascular system through the valve of a connector, and more specifically to reduce the risk of a drug being scraped off a drug-coated stent, the second aspect of the invention provides a connector for a haemostatic valve assembly, comprising a longitudinally extending main section having a longitudinally extending, through-going passage and a valve at a proximal end of the connector, the valve having an open state in which an elongate member may be inserted into the passage, and a closed state, the valve comprising an indicator for indicating the state of the valve. The indicator may provide an optical and/or a tactile feedback to an operator, so that the operator by looking at or by touching the valve may easily determine the state of the valve.

In a preferred embodiment, the valve includes a valve opener which is longitudinally displaceable along an outer surface of the main section of the connector, such that the state of the valve may be changed by displacing the valve opener in relation to the main section. The valve opener, or, in case of other embodiments, other displaceable means, may advantageously be arranged near the indicator which may comprise optical means for providing an optical appearance of at least a part of the connector in the open state which is different from an optical appearance of that part of the connector in the closed state. For example, the valve may comprise an elastomeric closure member, such as a silicone member, arranged to seal the proximal end of the connector in the closed state of the valve, the valve opener comprising a puncture member which extends co-axially with and at least partly inside said passage. The puncture member may be arranged such with respect to the closure member that it penetrates the closure member in the open state of the valve, the elastomeric closure member thereby closing about an outer surface of the puncture member, and such that it does not penetrate the closure member in the closed state of the valve. Such an embodiment of the valve is well suited for an embodiment of the valve opener which comprises a transparent portion and an opaque portion, and wherein the main section of the connector, at a proximal end thereof, comprises a coloured section which is covered by the opaque portion of the valve opener when the valve is in the open state, and which is visible through the transparent section when the valve is in the closed state. Thus, for example the coloured section may be clearly visible to the operator when the valve is in the closed state and completely hidden when the valve is in the open state. Accordingly, a superficial and rapid glance at the valve may allow the operator to determine the state of the valve.

Though not preferred, a so-called 'Touhy Borst' valve, which is known *per se*, and which comprises an elastomeric membrane having an opening through which the catheter extends and which is closed about the periphery of the catheter by rotation of a cap, may be provided as the haemostatic valve. However, from an ease-of-use point of view, the 'Touhy Borst' design has the disadvantage that it requires a separate introducer needle or tube to pass thorough the valve for opening the membrane, so that a catheter or stent can be introduced without damage. Therefore, as the introduction and common use of vascular stents, including balloon expandable stents and self-expanding stents, has resulted in increased attention to the friction in passing a device through the valve and to the need for maintaining a position of the stent on the balloon, so-called puncture valves have become more popular. Examples of such puncture valves are those described herein in connection with the preferred embodiments of the present invention, the valve disclosed in US patent No. 5,195,980, and the valve described in US patent No. 5,176,652.

It should be understood that the connector according to the second aspect of the invention, as generally discussed above, may also include the features of the first aspect of the invention. Embodiments of the connector comprising a side arm for connecting the connector to a manifold, i.e. so-called 'Y-connecter' embodiments, may, according to the invention, be comprised in a kit further comprising a side arm tubing for the side arm and possibly a stopcock.

Generally, embodiments of the connectors of the present invention may be designed to fit a wide variety of stents, including, but not limited to, Strecker Stents, Palmaz Stents, Wallstents, self-expanding Nitinol Stents, such as Bard Luminex Stents, Symphony Stents, Smart Stents and AVE SE Stents, Perflex Stents, AVE Stents, Intrastents, Instents, Herculink, and Dynalink. Likewise, the connectors of the present invention may be designed to fit a variety of catheters, including, but not limited to, Mainz balloon catheters, Monorail balloon catheters, PCTA catheters, and ultrasound catheters.

Brief description of the drawings

The above aspects of the invention will now be further described with reference to the drawings, in which:

Fig. 1 shows a longitudinal cross-section of a connector according to the invention,

Fig. 2 shows an exploded side view of the connector of Fig. 1 and an associated stopcock,

Fig. 3 shows a longitudinal cross-section of a valve incorporated in the connector of Figs. 1 and 2, the valve being in a closed state,

Fig. 4 shows the valve of Fig. 3 in an open state,

Fig. 5 shows a cross-section of the valve of Figs. 3 and 4, including an indicator for indicating a state of the valve,

Fig. 6 shows a longitudinal cross-section of a coloured member comprised in the indicator of the valve of Fig. 5.

Fig. 7 shows a longitudinal cross-section of an interconnection between a proximal and a distal part of the connector of Figs. 1 and 2,

Fig. 8 shows a longitudinal cross-section of a distal part of Fig. 7,

Fig. 9 shows a perspective view of the proximal part of Fig. 8.

Detailed description of the drawings

As it will be appreciated from the below description of a preferred embodiment of the invention, both of the above aspects of the invention may be comprised in a single embodiment.

A Y-connector 100, as shown in Figs. 1 and 2, comprises a proximal part 102 and a distal part 104, the proximal and the distal part co-extending in a longitudinal direction and being assembled in an end-to-end manner with a distal end portion 106 of the proximal part 102 being received in a proximal end portion 108 of the distal part 104. The distal part 104 is formed as a rotating luerlock with a first outer grooved or threaded portion 109, and a second, inner threaded portion 111. Within each of the proximal and the distal part, there is provided a longitudinally extending, through-going passage 110 and 112, respectively. When assembled, the proximal and the distal part together define a main section 114. At the interconnection between the proximal and the distal part, the distal part defines a projecting portion 116, preferably a barbed portion, which projects radially inwardly and engages a recessed portion 118 of the proximal part 102, the recessed portion 118 being in the form of a collar defined by a transition of the outer diameter of the proximal part 102. The interconnection will be further described below with reference to Figs. 7-9. The projecting portion 116 is shaped to provide a snap-locking of the distal part 104 onto the proximal part

102. When assembled, the proximal part and the distal part clamp an O-ring 120 between them, the O-ring being provided at a reduced-diameter section of the proximal part and at a corresponding widened-diameter section of an inner surface of the distal part. Side arm 122 is provided for connecting the connector 100 to a manifold (not shown) used for pressure monitoring, contrast media injection and/or saline flushing. As shown in Fig. 2, the connection from side arm 122 to the manifold may be provided via a stopcock 124 and a side arm tubing 126.

At its proximal end, the connector 100 of Fig. 1 comprises a valve 128 comprising an elastomeric closure member 130, a valve opener 132, and a puncture member 134 shaped to provide an elongate passage port which, in the closed state of the valve as depicted in Fig. 3, allows the closure member to seal the proximal end of the passage 110, whereas in the open state of the valve, as depicted in Fig. 4, the puncture member penetrates the elastomeric closure member 130 to allow a catheter or a stent (not shown) to pass through the valve. The puncture member 134 is, as shown in Figs. 3 and 4 integral with the valve opener 132, which may be longitudinally displaced along an outer surface of the proximal part 102, as indicated by arrows 138 in Fig. 1, so that in a most proximal position of the valve opener, the valve is in a closed state, as in Fig. 3, and in a most distal position of the valve opener, the valve is in an open state, as in Fig. 4. An indicator for indicating the state of the valve comprises a coloured member 136, see Fig. 2.

Fig. 5 shows a cross-section of the valve of Figs. 3 and 4, including an indicator for indicating a state of the valve. The indicator comprises a coloured member 136 which may, e.g., the colour of which may, e.g., be yellow or any other strong colour. A most proximal section 140 of the valve opener 132 is opaque, whereas a distal portion 142 of the valve opener is transparent. Hence, when the valve is in a closed state as illustrated in Fig. 5, the coloured member 136 is visible through the transparent portion 142. However, when the valve is in an open state, i.e. when the valve opener 132 is displaced to the position illustrated in Fig. 4, the opaque section 140 of the valve opener overlaps the coloured member 136, which is then essentially invisible to an operator. If, for example, the coloured member 136 has a strong yellow colour, it will be immediately apparent to an operator when the valve is in its closed state, thereby clearly indicating that no attempts should be made to insert a catheter or a stent through the valve, whereas no yellow colour will be visible when the valve is in its open state, thereby clearly indicating that a catheter or a stent may be safely passed through the valve. It should be understood that the valve may alternatively be designed such that the coloured member is visible when the valve is in its open state and invisible in the closed state.

The coloured member 136 is shown in detail in Fig. 6, from which it is apparent that a projecting portion, such as preferably a barbed portion 144, allows the coloured member 136 to be connected to the proximal part 102 of the connector via a snap-lock made possible thanks to the barbed portion exhibiting a radial elasticity and substantially no longitudinal elasticity. The radial elasticity may be provided by longitudinally extending slits in the member 136, such slits being formed essentially like those slits 148 which are provided in the area of the barbed portion of the distal part 104 of the connector, see Fig. 9. As illustrated in Fig. 5, the proximal part 102 defines a recessed portion in the form of a collar 146, so that when the member 136 and the proximal part 102 are interconnected, the barbed portion firmly secures the member 136 in relation to the proximal part 102.

The interconnection between the distal and proximal parts 102 and 104, respectively, is based on the same principle as the interconnection between the coloured member 136 and the proximal part 102, as described above with reference to Figs. 5 and 6. Thus, as illustrated in Fig. 7, the proximal part 104 has a barbed portion 116 engaging a collar 118 of the proximal part 102. An annular space 150 is available for the O-ring which is not shown in Fig. 7, but which is designated by reference numeral 120 in Fig. 1. The distal part 104 is shown in isolation in Figs. 8 and 9, from which it is also apparent that a proximal end portion of the distal part comprises several barbed portions 116 arranged along the periphery of the distal part 104 and with slits 148 therebetween, the slits providing a radial flexibility which allows the second part 104 with the barbed portions 116 to engage the collar 118 of the proximal part 102 in a snap-locking manner.

The operation of the embodiment of the connector 100 described above with reference to the drawings is as follows:

1. A manifold (not shown) is attached to the side arm 122 of the connector.
2. The distal end of the connector is connected to a proximal end of a guiding catheter (not shown).
3. The connector is flushed with saline to remove air bobbles. Flushing of the valve 128 is achieved when the valve is in its open state.
4. A pressure/infusion device (not shown) is attached to the manifold. In order to avoid air aspiration, it should be assured that all connections are secure.
5. The guiding catheter is introduced, following a guiding catheter introduction procedure which is usually recommended by a manufacturer of the guiding catheter.
6. A guide wire (not shown), or a guide wire and a dilatation catheter (not shown) is/are introduced into the connector. A metal guide wire insertion tool (not shown) should be used when the guide wire is inserted alone to protect a top of the guide wire. A PTCA dilatation catheter can be inserted alone without opening the valve. However, the valve should be

opened using the valve opener 132 for any device larger than a dilatation catheter, such as a stent, ultrasound catheter, etc.

7. Any procedure devised by the catheter or stent manufacturer is then followed.

The dimensions and other specifications of a preferred embodiment of the connector 100 are as follows:

Inner diameter of narrowest portion:	2.4 mm – 9.0 mm.
Maximum diameter of device to be inserted:	2.33 mm – 8.0 mm.
Minimum diameter of device to be inserted:	0.17 mm – 1.10 mm.
Maximum pressure resistance with PTCA catheter and guide wire:	8 Atm or with Percutan graft 1 atm.
Maxim pressure resistance without device:	21 Atm – 2 atm
Metallic insertion tool length:	10 cm – 2 cm
Metallic insertion tool inner diameter:	0.64 mm – 2.00 mm.

The number of the interval mentioned first refers to PTCA and the second number of the interval refers to AAA graft (Percutaneous-Abdominal Aortic Aneurysm stent graft).

CLAIMS

1. A connector (100) for a haemostatic valve assembly, comprising a longitudinally extending main section (114) having a proximal part (102) and a distal part (104), each of said parts having a longitudinally extending, through-going passage (110;112), the connector (100) further comprising connection means for providing a connection between the proximal part (102) and the distal part (104), whereby, when interconnected, the distal and proximal parts coextend in the longitudinal direction, said connection means comprising a projecting portion (116) which is integral with one of said parts (102;104) and which is adapted to engage a recessed portion (118) of the other one of said parts (102;104), so as to mutually secure the parts in the longitudinal direction.

2. A connector according to claim 1, wherein said projecting portion (116) is a barbed portion.

3. A connector according to claim 1 or 2, wherein the connection means provide a snap lock between said parts.

4. A connector according to claim 2 or 3, wherein an end portion (108) of the distal part (104) is adapted to receive an end portion (106) of the proximal part (102), the barbed portion (116) being provided at said end portion (108) of the distal part (102), the recessed portion (118) comprising a collar portion provided on an outer surface of the proximal part (102).

5. A connector according to claim 4, wherein the barbed portion (116) is formed by an outer wall of the distal part (104).

6. A connector according to any of claims 1-3, wherein an end portion (106) of the proximal part (102) is adapted to receive an end portion (108) of the distal part (104), the barbed projecting portion (116) being provided at said end portion (106) of the proximal part (102), the recessed portion (118) comprising a collar portion provided on an outer surface of the distal part (104).

7. A connector according to claim 6, wherein the barbed portion (116) is formed by an outer wall of the proximal part (102).

8. A connector according to any of the preceding claims, further comprising a sealing means (120) for providing a liquid-tight seal at the interconnection.

9. A connector according to claim 8, wherein the sealing means (120) comprises a resilient member, and wherein the proximal and distal parts (102;104), when interconnected, are arranged to clamp the resilient member between them.

10. A connector according to any of claims 1-9, wherein the interconnection is such that the distal part (104) and the proximal part (102) may rotate relative to each other around an axis extending in the longitudinal direction.

11. A connector according to claim 10, wherein the distal part (104) constitutes a rotatable luer.

12. A connector according to any of claims 1-11, wherein an outer wall of the distal part (104) is provided with a first threaded or grooved portion (109).

13. A connector according to any of claims 1-12, wherein an inner wall of the distal part (104) is provided with a second threaded portion (111).

14. A connector according to any of claims 1-13, comprising a side arm (122) for connecting the connector (100) to a manifold.

15. A kit comprising a connector according claim 14, and a side arm tubing (126) for the side arm (122) of the connector.

16. A kit according to claim 15, further comprising a stopcock (124) to be connected to one end of the side arm tubing (126).

17. A method for manufacturing a connector (100) for a haemostatic valve assembly, comprising a longitudinally extending main section (114) having a proximal part (102) and a distal part (104), each of said parts having a longitudinally extending, through-going passage (110;112), the connector further comprising connection means for providing a connection between the proximal part (102) and the distal part (104), whereby, when interconnected, the distal and proximal parts coextend in the longitudinal direction, said connection means comprising a projecting portion (116) which is integral with one of said parts (102;104) and which is adapted to engage a recessed portion (118) of the other one of said parts (102;104), the method comprising the step of providing a snap-lock between the projecting portion (116) and the recessed portion (118) for mutually securing the parts (102;104) in the longitudinal direction.

18. A method according to claim 17, comprising injection moulding the distal and proximal parts (102;104) from a plastics material.

19. Use of a snap-lock as an interconnection between a longitudinally extending proximal part (102) and a longitudinally extending distal part (104) of a main section (114) of a connector (100) for a haemostatic valve assembly, each of said parts having a longitudinally extending, through-going passage (110;112), the snap-lock comprising a projecting portion (116) which is integral with one of said parts (102;104) and which is adapted to engage a recessed portion (118) of the other one of said parts, so as to mutually secure the parts (102;104) in the longitudinal direction.

20. A connector (100) for a haemostatic valve assembly, comprising a longitudinally extending main section (114) having a longitudinally extending, through-going passage (110;112) and a valve (128) at a proximal end of the connector, the valve having an open state in which an elongate member may be inserted into the passage (110;112), and a closed state, the valve comprising an indicator (136;140;142) for indicating the state of the valve.

21. A connector according to claim 20, wherein the valve (128) comprises a valve opener (132) which is longitudinally displaceable along an outer surface of the main section (114) of the connector (100), such that the state of the valve (128) may be changed by displacing the valve opener (132) in relation to the main section (114).

22. A connector according to claim 21, wherein the indicator (136;140;142) comprises optical means for providing an optical appearance of at least a part of the connector (100) in the open state which is different from an optical appearance of that part of the connector in the closed state.

23. A connector according to claim 21 or 22, wherein the valve (128) further comprises an elastomeric closure member (130) arranged to seal the proximal end of the connector (100) in the closed state of the valve (128), and wherein the valve opener (132) comprises a puncture member (134) which extends co-axially with and at least partly inside said passage (110;112), and which is arranged such with respect to the closure member (130) that it penetrates the closure member (130) in the open state of the valve, the closure (130) member thereby closing about an outer surface of the puncture member (134), and such that it does not penetrate the closure member (130) in the closed state of the valve (128).

24. A connector according to any of claims 21-23, wherein the valve opener (132) comprises a transparent portion (142) and an opaque portion (140), and wherein the main section

(114) of the connector, at a proximal end thereof, comprises a coloured section (136) which is covered by the opaque portion (140) of the valve opener when the valve is in the open state, and which is visible through the transparent section (142) when the valve is in the closed state.

25. A connector according to claim 24, wherein the coloured section (136) is comprised in a coloured member which is connected to the main section (114) via a connection having a projecting portion (144) which is integral with one of said sections (114;136) and adapted to engage a recessed portion (146) of the other one of said sections (114;136), so as to mutually secure the sections (114;136) in the longitudinal direction.

26. A connector according to any of claims 20-25, comprising a side arm (122) for connecting the connector (100) to a manifold.

27. A kit comprising a connector (100) according claim 26, and a side arm tubing (126) for the side arm (122) of the connector.

28. A kit according to claim 27, further comprising a stopcock (124) to be connected to one end of the side arm tubing (126).

29. Use of an indicator (136;140;142) for indicating a closed or open state of a haemostatic valve (128) integrated in a connector (100) of a haemostatic valve assembly.

30. Use according to claim 29, wherein optical means (136;140;142) are employed for providing an optical appearance of at least a part of the connector (100) in the open state which is different from an optical appearance of that part of the connector in the closed state.

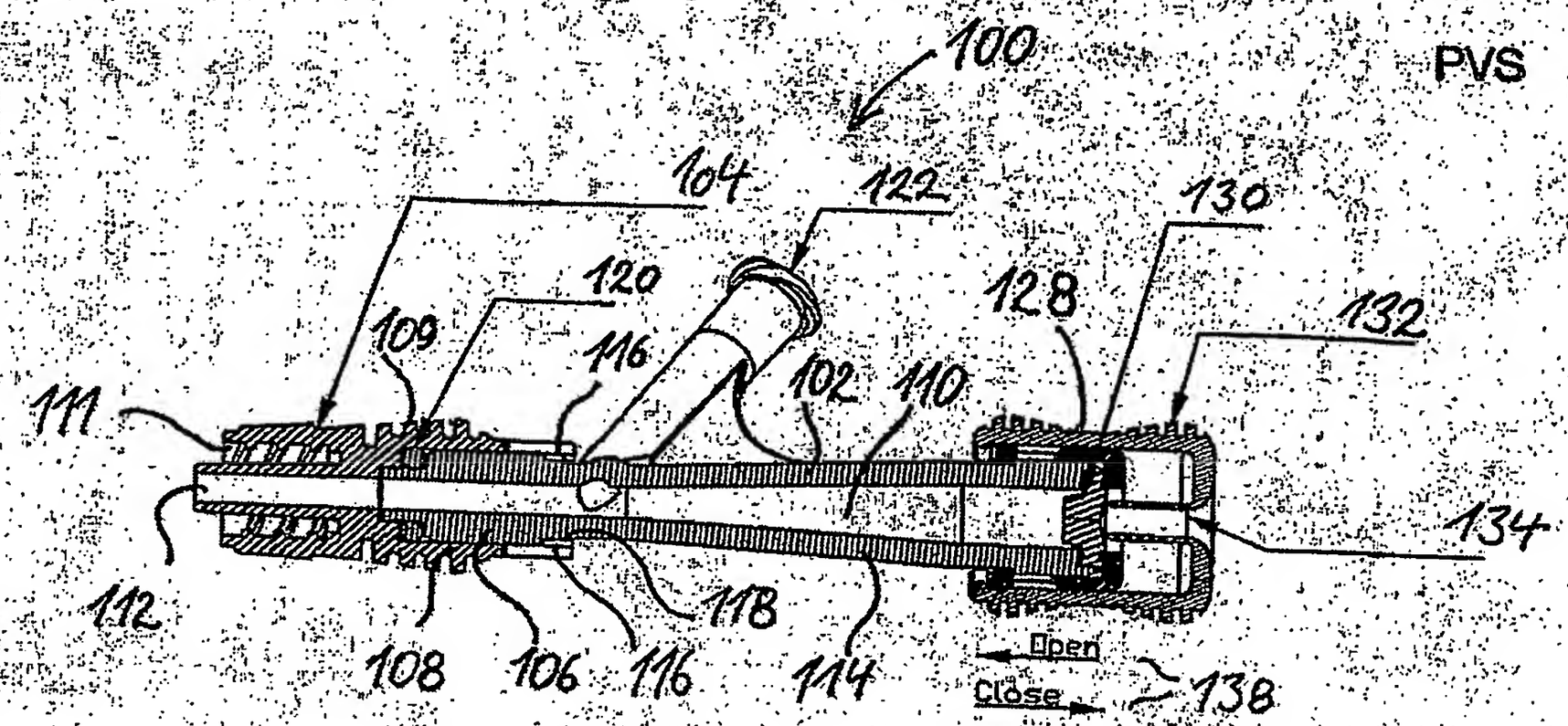

Fig. 1

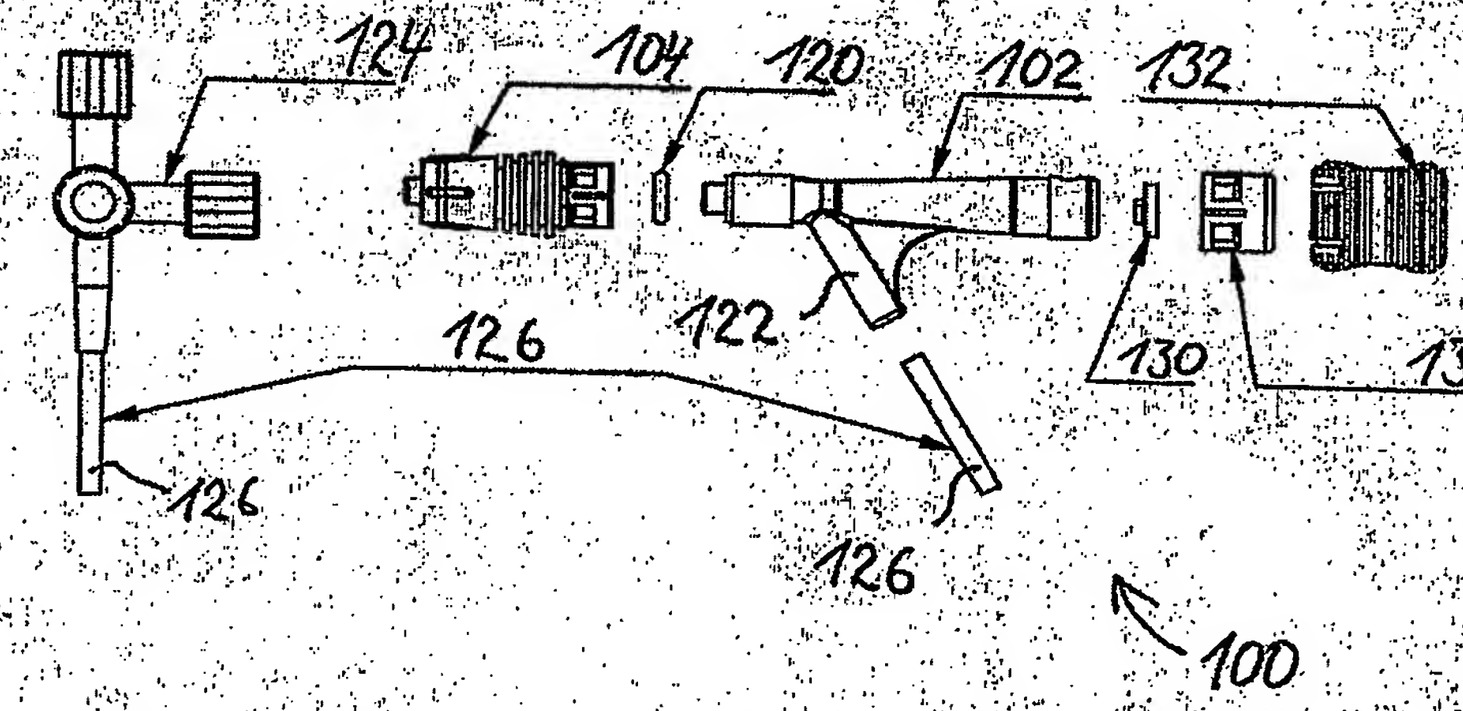

Fig. 2

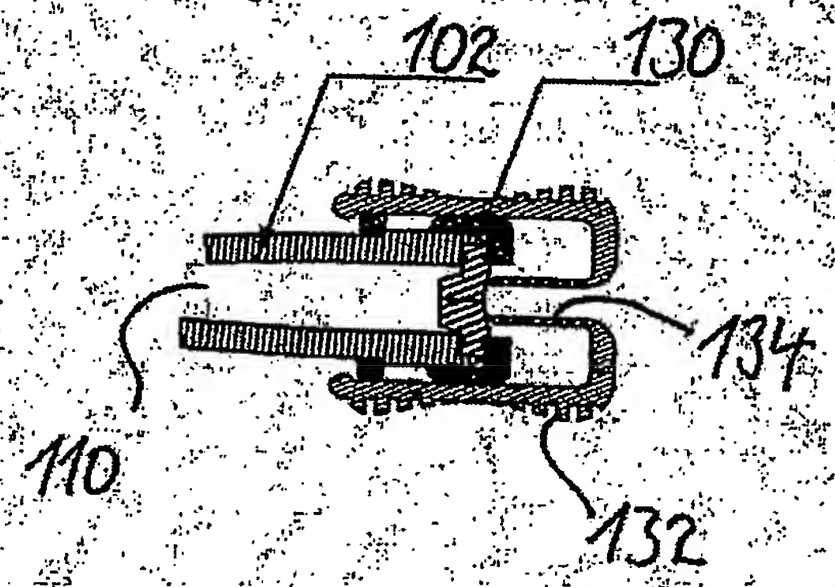

Fig. 3

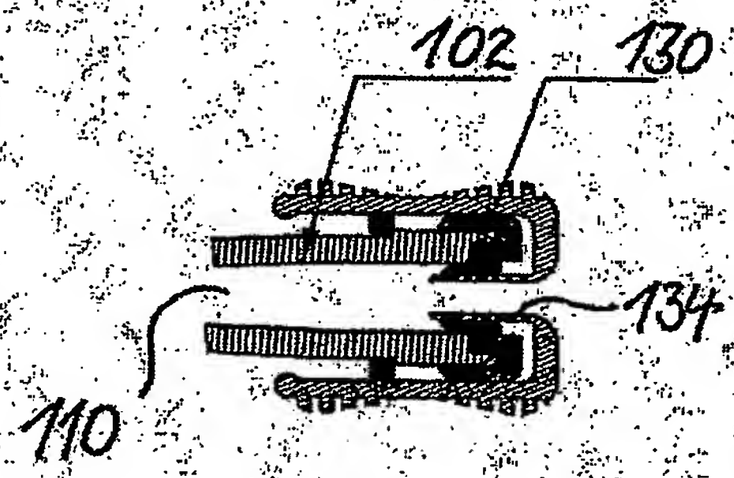

Fig. 4

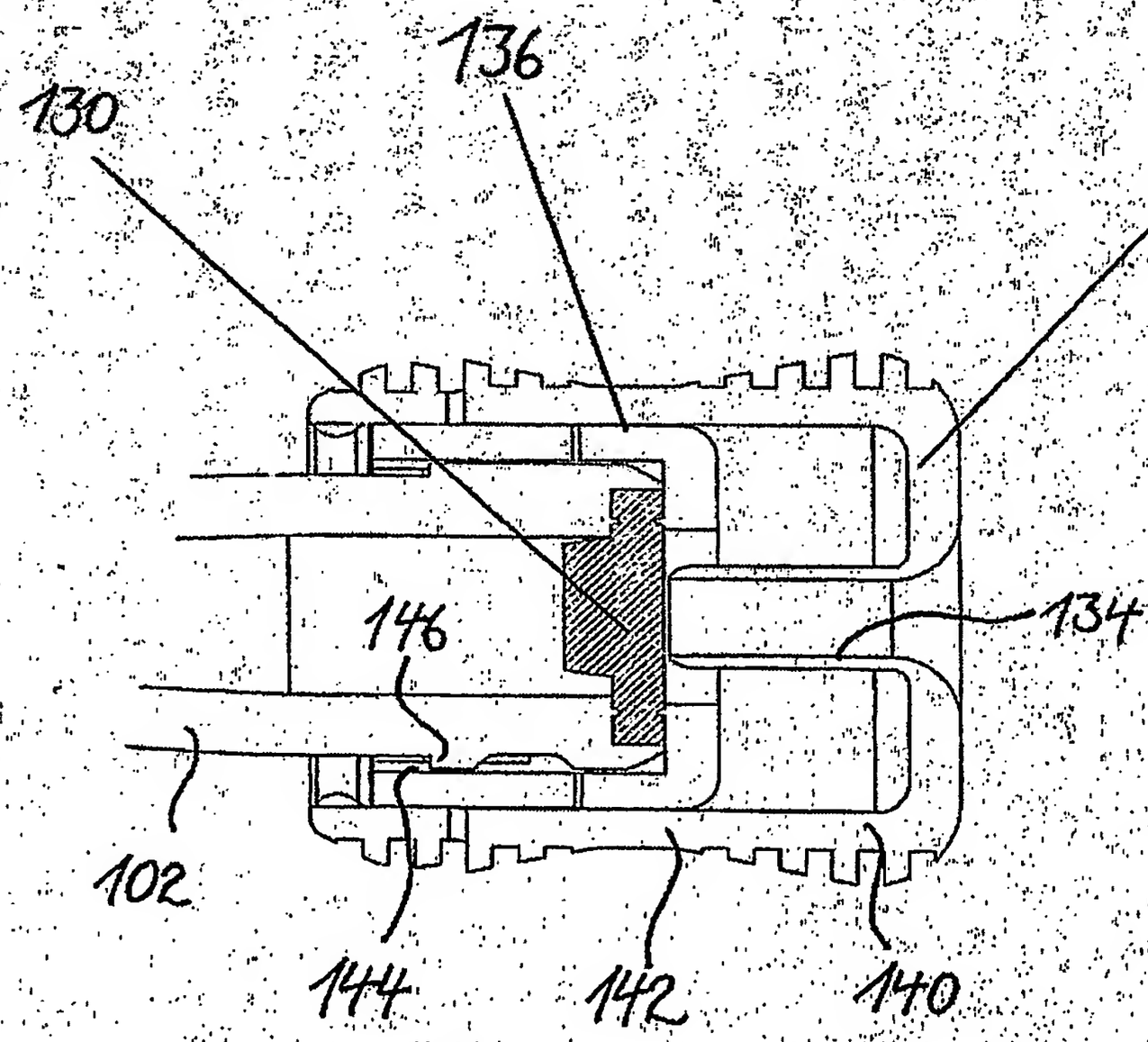

Fig. 5

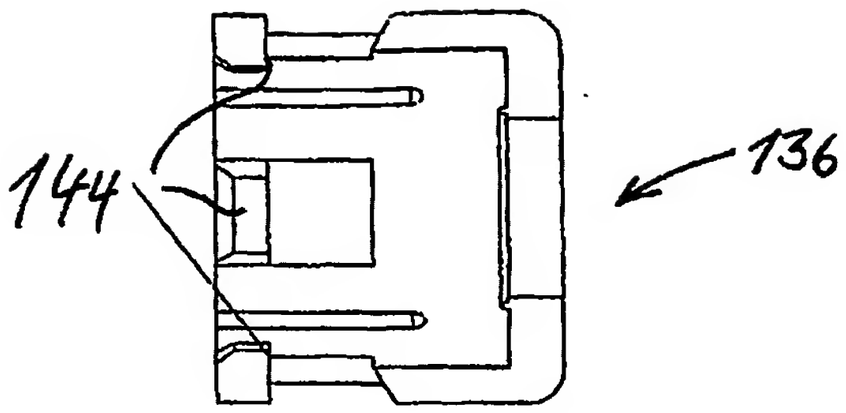

Fig. 6

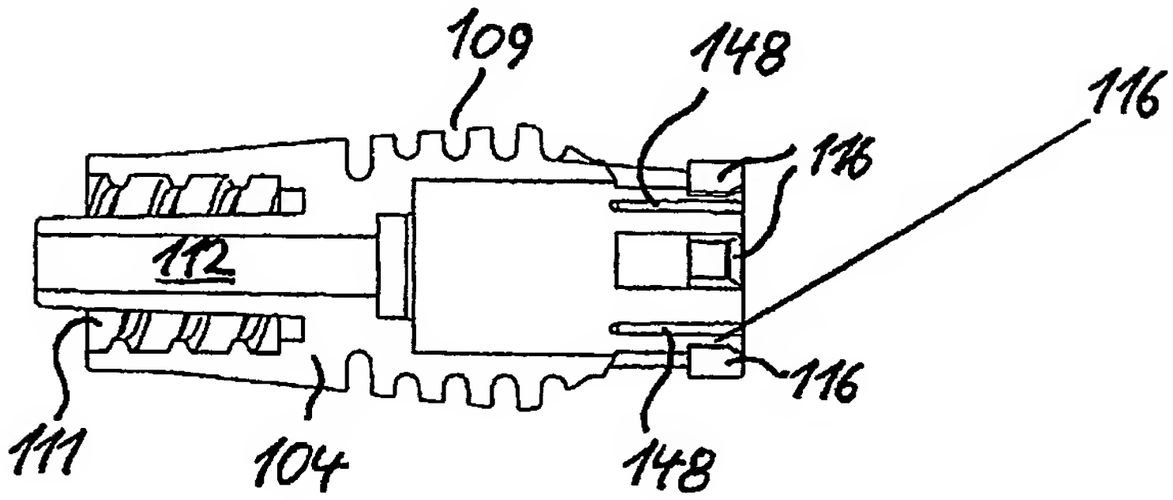

Fig. 7

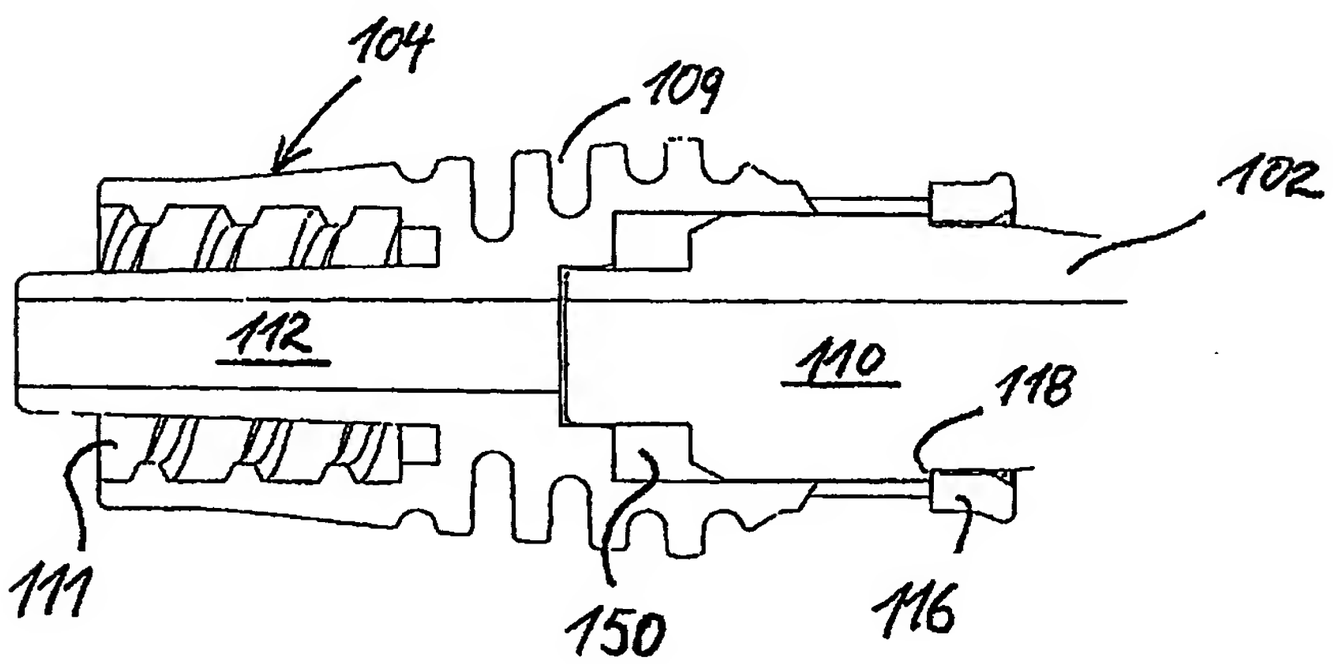

Fig. 8

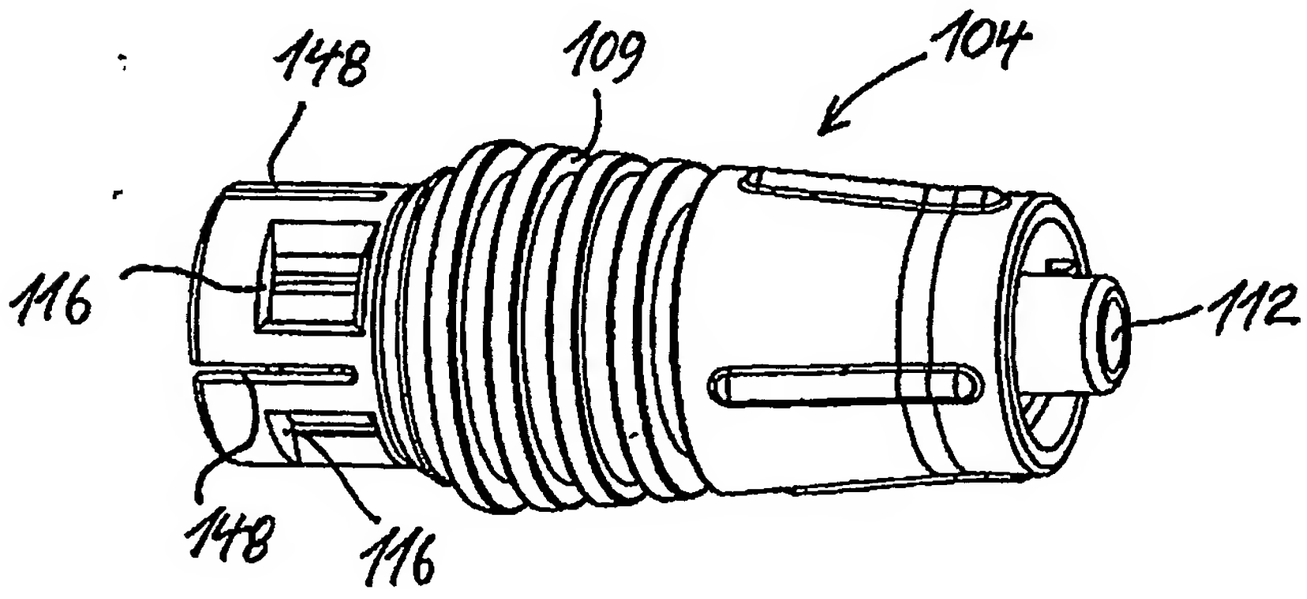

Fig. 9